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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,962	08/11/2000	Lawrence H. Thompson	500731.01	8001

27076 7590 07/22/2004

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/637,962	THOMPSON, LAWRENCE H.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66,68,76-85,117-127,129 and 130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66,68,76-85,117-127,129 and 130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 05 May 2004 has been entered in full. Claims 66, 68, 76-85, 117-127, 129 and 130 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103(a)

Claims 66, 68, 76-85, 117-127, 129 and 130 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kveder *et al.,* Farmacevtski Vestnik 47/SPEC. ISS. pages 163-171 (1996). The basis for this rejection is set forth at pages 2-5 of the previous Office Action (05 February 2004, Paper No. 13).

Applicant argues that at the time the invention was made, one skilled in the art would have expected that a glycoprotein made from the same EPO gene as EPO Alfa and Beta, having very similar size and being made in a similar mammalian culture system would have similar properties to EPO Alfa and EPO Beta. Applicant maintains that one would have expected that EPO Omega would have a similar, if not the same, function and side effects as Epoietins Alfa and Beta. Applicant argues that Kveder *et al.* report that 17% of the patients experienced increased blood pressure, 1 in 30 had to suspend treatment due to allergic reaction, and 1 in 30 reported pain during administration. Applicant states that these results are consistent with those reported in sections 3.1 and 3.2 for administration of EPO Alfa and/or Beta.

Applicant argues that one who is non-responsive and adversely affected when treated with Epoietin Alfa and/or Beta, would also be non-responsive and adversely affected when treated with Epoietin Omega. Applicant maintains that a skilled artisan would not have expected that EPO Omega would exhibit significantly more potency, higher serum concentration over clearance time, and lower doses in both initial treatment and maintenance compared to EPO Alfa and Beta. Applicant states that a skilled artisan could not have predicted that increase in blood pressure, which is one of the major adverse effects associated with EPO Alfa and Beta would be absent from the treatment with EPO Omega and that EPO omega would be effective in subjects non-responsive to or adversely affected by treatment with other Epoietins. Applicant asserts that the differences in function and side effects exhibited by EPO Omega in comparison to Epoietins Alfa and Beta would not have been expected by a skilled artisan. Thus it would not have been obvious to treat patients who are non-responsive or adversely affected by Epoietin Alfa and/or Beta with EPO Omega. Applicant argues that the non-responsiveness and side effects experienced by a number of patients who were treated with Epoietin Alfa or Beta would have led one skilled in the art away from trying to treat such patients with EPO Omega because they would have been expected to react similarly regardless of the type of EPO administered.

Applicants' arguments have been fully considered but not deemed persuasive for the following reasons. The instant claims are drawn to a method for treating an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells, the

recombinant erythropoietin consisting of Epoietin Omega, wherein the amount of recombinant erythropoietin administered is selected to provide a therapeutic benefit within a treatment period, and wherein the subject is non responsive when treated with a therapeutic amount of Epoietin Alfa or Beta.

Kveder *et al.* teach clinical trials with Epoietin Omega. Kveder *et al.* teach the administration of Epoietin Omega (recombinantly produced in baby hamster kidney cells) to patients requiring hemodialysis two or three times per week and who also had hemoglobin levels below 85 grams per liter or below 90 grams/liter (anemia/renal condition). Some of the primary objectives of Kveder *et al.* were to raise hemoglobin and hematocrit levels. Kveder *et al.* teach that the appearance of hypertension has been described in ***30 to 35%*** of the patients and is an important side effect of treatment with forms of r-Hu-EPO other than Epoietin Omega. Contrary to Applicant's assertion, Kveder *et al.* do state that ***17%*** of the patients treated with Epoietin Omega experienced increased blood pressure, but it was controllable and there was no need to withdraw treatment with EPO omega. Thus, Kveder *et al.* teach that patients treated with Epoietin Omega were less likely to experience hypertension than patients treated with other EPO forms.

Kveder *et al.* teach a method for treating anemic conditions in subject comprising administering EPO omega, but do not implicitly state, "wherein the subject is non responsive or adversely affected when treated with a therapeutic amount of Epoietin Alfa or Beta". However, it would be obvious that if a subject is non-responsive or adversely affected when treated with Epoietin Alfa or Beta, one skilled in the art, would

clearly attempt to try another form of Epoietin, such as Epoietin Omega as taught by Kveder *et al.* The motivation and expected success is provided by Kveder *et al.*, who state that patients tolerated Epoietin Omega treatment well. Kveder *et al.* state that the clinical trial of efficacy and tolerance for treatment with Epoietin Omega showed that it is possible to achieve a correction in anemia within a relatively short period of time in patients with chronic kidney failure who are being treated with dialysis. Only one patient suffered an allergic reaction and only one patient reported pain during subcutaneous administration. Kveder *et al.* state that the doses need to accomplish the stated objectives were within the range that had been anticipated by the manufacture in a large majority of patients and since a compound and all of its properties are inseparable {In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)}, Epoietin Omega would be expected to increase RBC, HCT, hemoglobin and vigor. Furthermore, an EPO patient that experiences hypertension as a side effect is "adversely affected" by the EPO treatment, and Kveder *et al.* disclosure of a lower incidence of hypertension in patients treated with EPO omega, clearly suggest use of EPO Omega.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

RMD
7/19/04

ELIZABETH KEMMERER
PRIMARY EXAMINER